



BILLING CODE 6560-50-P

## **ENVIRONMENTAL PROTECTION AGENCY**

### **40 CFR Part 180**

**[EPA-HQ-OPP-2017-0351; FRL-10013-43]**

### **Deoxyribonucleic Acid (DNA) Sequences; Exemption from the Requirement of a Tolerance**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes an exemption from the requirement of a tolerance for residues of deoxyribonucleic acid sequences consisting solely of adenine, cytosine, guanine, and thymine, of 300 or fewer base pairs, and which do not contain start codons or regulatory sequences necessary for the initiation of transcription or translation when used as an inert ingredient (product identifier) in pesticide formulations applied to growing crops and to raw agricultural commodities after harvest at a concentration not to exceed 1.0 parts per million (ppm). InvisiDex Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of deoxyribonucleic acid that satisfy the terms of the exemption.

**DATES:** This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-

HQ-OPP-2017-0351, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Marietta Echeverria, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: [RDfRNotices@epa.gov](mailto:RDfRNotices@epa.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. Does this action apply to me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

*B. How can I get electronic access to other related information?*

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at [http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).

*C. How can I file an objection or hearing request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2017-0351 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-

OPP-2017-0351, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

For the latest status information on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

## **II. Petition for Exemption**

In the **Federal Register** of September 15, 2017 (82 FR 43352) (FRL-9965-43), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN-11062) by InvisiDex Inc., 1129 Maricopa Hwy #217, Ojai, CA 93023. The petition requested that 40 CFR 180.910 be amended by establishing an exemption from the requirement of a tolerance for residues of deoxyribonucleic acid (CAS Reg. No. 9006-49-2) when used as an inert ingredient (product identifier) in pesticide formulations applied to growing crops and to raw agricultural commodities after harvest at a concentration not to exceed 1.0 parts per million (ppm). That document referenced a summary of the petition prepared by InvisiDex Inc., the petitioner, which is available in the docket, <http://www.regulations.gov>. One comment was received on the notice of filing. EPA's response to this comment is discussed in Unit V.B.

## **III. Inert Ingredient Definition**

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR

153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term “inert” is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

#### **IV. Aggregate Risk Assessment and Determination of Safety**

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(c)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human

health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for deoxyribonucleic acid sequences including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with deoxyribonucleic acid sequences follows.

#### *A. Toxicological Profile*

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by deoxyribonucleic acid sequences as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

Deoxyribonucleic acid (DNA) is routinely synthesized and degraded by almost all living cells. DNA breakdown into constituent nucleic acids continuously occurs in living cells. Purine

and pyrimidine nucleosides can either be degraded to waste products and excreted or can be salvaged as nucleotide components. Therefore, metabolites of DNA do not pose a toxicological risk.

DNA sequences used as product identifiers contain the same nucleic acids as DNA present in the environment, and humans routinely consume DNA as a component of food.

All humans are exposed to DNA throughout their lives as part of their diet, in which DNA is metabolized to its component nucleic acids, which are then further used by the body for essential metabolic processes. Consumption of nucleic acids in food has not been associated with any toxic effects. Thus, because the DNA sequences that are used as product identifier contain the same nucleic acids, (adenine, cytosine, guanine and thymine) as found in DNA, consumption of food containing residues of DNA sequences that are used as product identifiers are not expected to present a toxic effect.

There is a potential for extracellular or exogenous DNA to interact with microorganisms in the environment such as bacteria. This interaction could result in the formation of exogenous proteins or other materials that could potentially be harmful to humans. However, the DNA sequences proposed for use by the petitioner lack start codons or regulatory sequences necessary for the initiation of transcription or translation. They cannot encode a protein nor integrate with other genetic sequences and, as such, cannot lead to the formation of exogenous proteins or other materials. Moreover, the restriction of exempted DNA to be comprised of 300 base pairs or less will also limit the ability of DNA to replicate in the environment. Finally, the DNA sequence's ability to cause replication are further limited by lack of stability and integrity of extracellular DNA in the environment. Extracellular DNA routinely degrades in the environment when it is exposed to harsh environmental conditions such as mechanical shearing and UV degradation.

### *B. Toxicological Points of Departure/Levels of Concern*

As no human health toxicity endpoints have been selected, a quantitative assessment is not being conducted.

### *C. Exposure Assessment*

All humans are exposed to DNA throughout their lives as part of diet. As an inert ingredient in pesticide products, DNA sequences may result in residues in or on food. DNA sequences may be used as an inert ingredient (product identifiers) in pesticide formulations that are used in residential setting, however because DNA sequences are unlikely to cross the skin barrier or be available via inhalation. Therefore, inhalation and dermal exposure are not of concern.

Due to the lack of toxicity, EPA does not expect these exposures to pose any risk of harm. DNA sequences used as product identifiers will also be limited to 1 ppm in pesticide formulations, with any resultant exposure to humans resulting from such use being negligible.

### *D. Safety Factor for Infants and Children*

Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.



Due to the lack of toxicity or any threshold effects, an FQPA SF is not needed to protect the safety of infants and children.

#### *E. Aggregate Risks and Determination of Safety*

Taking into consideration all available information on deoxyribonucleic acid sequences consisting solely of adenine, cytosine, guanine and thymine, of 300 or fewer base pairs, and which do not contain start codons or regulatory sequences necessary for the initiation of transcription or translation when used as an inert ingredient (product identifier), EPA has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to deoxyribonucleic acid sequences under reasonably foreseeable circumstances. Therefore, the establishment of an exemption from tolerance under 40 CFR 180.910 for residues of deoxyribonucleic acid sequences as described in the exemption when used as an inert ingredient in pesticide formulations applied to growing crops and to raw agricultural commodities after harvest at a concentration not to exceed 1.0 ppm, is safe under FFDCA section 408.

### **V. Other Considerations**

#### *A. Analytical Enforcement Methodology*

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residues of DNA sequences in or on any food commodities. EPA is establishing limitations on the amount of DNA sequences that may be used in pesticide formulations applied pre- and post-harvest. These limitations will be enforced through the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”), 7 U.S.C. 136 *et seq.* EPA will not register any pesticide formulation for food use that exceeds 1 ppm by weight of DNA sequences in the final pesticide formulation.

### *B. Response to Comments*

One comment generally asserting that pesticides are toxic and should not be allowed on food was received in response to the notice of filing. Although the Agency recognizes that some individuals believe that pesticides should be banned on agricultural crops, the existing legal framework provided by section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) authorizes EPA to establish tolerances when it determines that the tolerance is safe. Upon consideration of the validity, completeness, and reliability of the available data as well as other factors the FFDCA requires EPA to consider, EPA has determined that this exemption is safe. The commenter has provided no information to indicate that the exemption would not be safe.

### *C. Revisions to Petitioned-for Tolerances*

Based on clarification as to the composition of the DNA that would be utilized as a product identifier, the petitioner provided additional descriptive criteria that have been incorporated by the Agency into the tolerance exemption expression to ensure that the DNA sequences used as product identifiers would not be taken up by organisms in the environment and used for the production of proteins that could be harmful to human health.

## **VI. Conclusions**

Therefore, an exemption from the requirement of a tolerance is established under 40 CFR 180.910 for deoxyribonucleic acid sequences consisting solely of adenine, cytosine, guanine and thymine, of 300 or fewer base pairs, and which do not contain start codons or regulatory sequences necessary for the initiation of transcription or translation when used as an inert ingredient (product identifier) in pesticide formulations applied to growing crops and to raw agricultural commodities after harvest at a concentration not to exceed 1.0 ppm.

## **VII. Statutory and Executive Order Reviews**

This action establishes an exemption from the requirement of a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997), nor is it considered a regulatory action under Executive Order 13771, entitled “Reducing Regulations and Controlling Regulatory Costs” (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct

effect on States or tribal governments, on the relationship between the National Government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

#### **VIII. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

#### **List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 27, 2020.

**Marietta Echeverria,**

*Acting Director, Registration Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 180--TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL  
RESIDUES IN FOOD**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. In §180.910, add alphabetically the inert ingredient “Deoxyribonucleic acid (DNA) sequences consisting solely of adenine, cytosine, guanine and thymine, of 300 or fewer base pairs, and which do not contain start codons or regulatory sequences necessary for the initiation of transcription or translation” to table 1 to read as follows:

**§ 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.**

\* \* \* \* \*

**Table 1 to 180.910**

<b>Inert ingredients</b>	<b>Limits</b>	<b>Uses</b>
* * * * *	*	*
Deoxyribonucleic acid (DNA) sequences consisting solely of adenine, cytosine, guanine and thymine, of 300 or fewer base pairs, and which do not contain start codons or regulatory sequences necessary for the initiation of transcription or translation	No more than 1 ppm in pesticide formulation	Product identifier
* * * * *	*	*